APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,774	02/27/2002	Anna Sylvan	14255.01	2027

30873   7590   09/10/2004

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INTELLECTUAL PROPERTY DEPARTMENT
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EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 30 August 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may <u>only</u> be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

<u>PERIOD FOR REPLY</u> [check either a) or b)]

a) ☒ The period for reply expires <u>5</u> months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1.☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2.☒ The proposed amendment(s) will not be entered because:

   (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☒ they present additional claims without canceling a corresponding number of finally rejected claims.

      NOTE: *See Continuation Sheet.*

3.☐ Applicant's reply has overcome the following rejection(s): _____.

4.☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5.☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet.*

6.☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7.☒ For purposes of Appeal, the proposed amendment(s) a)☒ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: *NONE.*

   Claim(s) objected to: *NONE.*

   Claim(s) rejected: *1,3-15,17 and 19-23.*

   Claim(s) withdrawn from consideration: *NONE.*

8.☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9.☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10.☐ Other: _____

JEANINE A. GOLDBERG
PATENT EXAMINER

Continuation of 2. NOTE: Claim 1 has been amended to require adding non-chain terminating. This limitation was not previously searched or considered. Further, the response has added LCaims 24-25 which were not previously searched or considered with respect to bioluminetrically. .

Continuation of 5. does NOT place the application in condition for allowance because: The newly amended claims have not been entered, therefore, the arguments are moot.

However, with respect to the 103 rejections, Nyren speficially teaches using ddNTP's which was well established for use in polymorphism or allele detection. Further, Claim 15 of Nyren is specifically directed to a method for identification of a base in a single target position in a DNA sequence which would be indicative of SNPs or alleles or polymorphisms.

The response asserts that the method of Nyren would have been only suitable for homozygous or heterozygous sample from a single individual. This argument does not appear to provide any evidence why the pyrosequencing ehtod would not been sensitive and specific in a pooled sample. The attorney arguments of unexpected resulsts should be supported by evidence.

The response asserts that Lapidus does not determine frequency of an allele. This argument has been thoroughly reviewed, but is not found persusasive because if Lapidus determine whether normal heterozygosity has been lost, then Lapidus has determined the frequency of the lost allele to be zero.

WIth respect to the declaration filed by Anna Sylvan to swear out Breen. The declaration has not been reviewed or considered, as there no good and sufficient reason why the declaration could not have been filed earlier. .